This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

# DRAFT GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS

# FOR

# MENSTRUAL TAMPONS

OBSTETRICS-GYNCEOLOGY DEVICES BRANCH
DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT,
AND RADIOLOGICAL DEVICES
OFFICE OF DEVICE EVALUATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MAY 25, 1995

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## Introduction

The purpose of this document is to outline the requirements for a 510(k) submission for menstrual tampons. This document is intended to cover the critical aspects of the submission to assist manufacturers in preparing their 510(k). However, additional information not identified in this document may occasionally be required to demonstrate substantial equivalence.

Menstrual tampons intended for reuse have not been classified and FDA is unaware of any pre-Amendments re-usable menstrual tampons. Over the years, FDA has found a number of such products to be not substantially equivalent to conventional menstrual tampons, and these products are then classified by statute into Class III. Before submitting a 510(k) to FDA for a re-usable tampon, please contact Mr. Colin Pollard, Chief, OB/GYN Devices Branch at (301) 594-1180.

## I. Device Identification

A. Device Name: _____

Provide both the trade or proprietary name of the tampon as well as the common or usual name for the device.

B. Predicate Device Name: _____

Identify the legally marketed menstrual tampons to which the new menstrual tampons will be compared. Be as specific as possible, e.g., proprietary and common name, manufacturer, model number, 510(k) reference number, pre-Amendments status, etc. The 510(k) should include a tabbed section with product literature (description, specifications, labels & labeling, etc.) from the predicate device.

## II. Establishment Registration # :

_____

Contact Person: _____
Title: _____
Telephone: _____

## III. Classification:

Class II (Special Control) for Menstrual Tampon

## IV. § 514 Performance Standards:

Non Applicable

## V. Device Description, Intended Use, and Directions for Use (Labeling)

*A. Device Description*

1. Device Diagram(s) and Dimensions

   Provide a complete description, including diagram(s), of the tampon. On each diagram, label the dimensions and materials of each part, including the pledget, cover, string, and applicator. Provide a cross-sectional diagram to illustrate the design and dimensions of the tampon. It may be useful to label these diagrams with additional information or to include additional diagrams to further clarify the information requested below.

2. Physical Properties

   a. Dimensions and Weight

      Provide specifications, including tolerances, for the following:

      • length and diameter of tampon pledget, string, and applicator
      • pledget weight (grams)

   b. Absorbency

      Provide tampon absorbency (in grams) by measuring the absorbency of individual tampons using the test method specified in 21 CFR 801.430 (f)(2). (See Appendix A)

3. Device Materials

   a. Provide the complete chemical and physical specifications for all materials from which the tampon (including applicator) is made. If color additives are used, identify the chemical composition, color index number, and color additive listing (21 CFR reference).

   b. Provide procedures to monitor the finished menstrual tampons including applicators and pads for the presence of dioxin and

furans; include testing protocol, data, and product sampling procedure.

c. Provide detailed chemical composition, chemical specifications, and quantity (in μg) of finishing and anti-wicking agents.

d. Provide the chemical composition of each component of the fragrance or other additives, if any, used in the tampon (including applicator).

4. Preclinical Toxicological Testing

a. Provide results of toxicity testing on the tampon in its final manufactured form, in accordance with International Standard 10993, "Biological Evaluation of Medical Devices Part 1 : Evaluation and Testing". For all testing, provide copies of the protocols and raw data.

In particular, provide a detailed description of the following tests, including raw data using polar and nonpolar extracts. Please consult with the Ob/Gyn Devices Branch before substituting a different test for any of the tests listed below.

- cytotoxicity
- acute systemic toxicity
- chronic and subchronic toxicity
- mucosal irritation
- delayed sensitization

These tests are recommended for new materials. If the device is made of materials that have been well characterized chemically and physically in the published literature, and have a long history of safe use, the Ob/Gyn branch will accept justification for not conducting some or all of the suggested tests.

b. Provide toxicity information on the individual chemicals used as fragrance or deodorant for the scented menstrual tampon.

c. If the tampon material, including any finishing agent or anti-wicking agent, is not already used in legally marketed menstrual tampons in the U.S., provide the following information:

(1) Provide results from *in vitro* testing to demonstrate that the

tampon, in its final manufactured form, will not enhance the growth of Staphylococcus Aureus or increase the production of TSST-1 toxin. Specify the test conditions, including cell culture medium and strain of S. Aureus. This report should include a detailed description of the test methodology, as well as the raw data and study conclusions.

(2) Provide results from *in vitro* testing to demonstrate that the tampon, in its final manufactured form, will not alter the growth of normal vaginal microflora. Specify the test conditions, including the cell culture medium and the various strains of microorganisms tested. This report should include a detailed description of the test methodology, as well as the raw data and study conclusions.

5. Clinical Safety Testing

If the design configuration, material(s), or product claims vary significantly from tampons (including applicators) already on the market, it may be necessary to conduct clinical testing. Such testing might address human safety considerations, e.g., irritation/allergy, effects on vaginal microflora, abrasions, ulceration, and laceration.

As part of clinical testing, each subject should undergo a colposcopic examination by a physician before and after the menses for adverse events relating to tampon use. For further guidance on conducting quality pelvic examinations, you may refer to World Health Organization (WHO) draft guidance for colposcopic examinations. (See Appendix B)

*B. Intended UseIntended Use*

As a Class II device, the menstrual tampon is defined as follows (21 CFR 884.5460 and 21 CFR 884.5470):

> "... a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge..."

Provide a statement of the intended use of the menstrual tampon that is consistent with the definition above. Product labeling should reflect this same intended use.

*C. LabelingLabeling*

Provide labeling for the menstrual tampon to address the following:

1. Selection of a Tampon
2. Absorbency (in grams) [21 CFR 801.430]
3. Insertion
4. Duration of Use (See Appendix C)
5. Removal and Disposal
6. Adverse Effects - Toxic Shock Syndrome Warnings
7. For scented tampons, include a warning statement that if an allergic reaction and/or irritation occurs from using this device, the consumer should discontinue use and consult a medical professional for evaluation of potential irritation and sensitization.

Device labeling should follow the regulatory specifications in "User labeling for Menstrual Tampons" (U.S. 21 CFR 801.430). (See Appendix B) For further general guidance on labeling requirements, you may refer to FDA's guidance manual, "Labeling: Regulatory Requirements for Medical Devices" (HHS Publication FDA-89-4203), and "Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care."

## VI. Comparison Statement of Substantial EquivalenceComparison Statement of Substantial Equivalence

Provide a discussion of similarities and differences of the tampon and applicator to those of the specified predicate device(s), particularly with respect to design, length, diameter, absorbency, materials and physical properties. Compare the chemical composition, including finishing and anti-wicking agent, to that of the marketed tampons. To assist in the evaluation of the 510(k), a comparison chart is included as Appendix D. Complete the comparison chart. Add other descriptive parameters, as necessary, to complete this comparison.

Any innovative or special feature to either the tampon or the applicator requires a thorough discussion of substantial equivalence. As stated in Section V. A. 5. above, such differences may also necessitate a small clinical trial to demonstrate substantial equivalence. Neither the comparison charts nor the substantial equivalence discussion of similarities and differences will independently fulfill the 510(k) requirements. Rather, each should complement the other in providing a total basis for substantial equivalence.

In evaluating substantial equivalence, FDA will emphasize the intended use and technological characteristics of the device compared to the predicate device.

## VII. Consequences and Effects of Changes, Modifications, or New Uses Consequences and Effects of Changes, Modifications, or New Uses

Guidance concerning device modifications is available in the draft guidance entitled "Deciding When to Submit a 510(k) for Change to an Existing Device" (4/8/94). A copy is available from Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597.

### *A. Changes Requiring a 510(k) Submission Changes Requiring a 510(k) Submission*

If a device has undergone a change or modification that could significantly affect the safety or effectiveness of the device, or if the device is to be marketed for a new or different intended use, a new 510(k) must be submitted. Scientific rationale should be provided for these significant modifications, as well supporting preclinical and/or clinical studies that demonstrate that these modifications do not adversely affect safety or effectiveness.

The following list comprises those changes considered to require a new 510(k) submission for tampons. This list is not exhaustive and is subject to change.

- New Intended Use
- New Device Material(s)
- Significant Design Modifications

### *B. Changes Not Requiring a 510(k) SubmissionChanges Not Requiring a 510(k) Submission*

Changes to a menstrual tampon that are minor and <u>do not significantly affect the safety or effectiveness of the device</u> do not require a new 510(k). It should be noted that while the following list identifies modifications that are currently considered to <u>not</u> require a new 510(k) submission for tampons, it is not an exhaustive list and does not necessarily represent a guide for changes to any other device.

- Minor Design Modifications
- Changing the Ratio of Currently Used Absorbency Material (i.e., Cotton vs Rayon)

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## Appendix D

# Menstrual Tampon
# Substantial Equivalence Comparison Chart

| Comparison Element | New Device | Predicate Device(s) |
|---|---|---|
| Device Name | | |
| Manufacturer | | |
| 510(k) Number | | |
| Intended Use | | |
| Device Design<br>(e.g., shape/size of tampon & applicator) | | |
| Component Materials | | |
| Dimensions<br>· Length<br>· Diameter | | |
| Absorbency(grams),<br>· Maximum<br>· Minimum | | |
| Required Accessory Devices, if any | | |
| Other Features | | |